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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
OFFICE OF THE DIRECTOR

Adopted New Rules: N.J.A.C. 13:45A-35

Prescription Monitoring Program

Proposed: November 16, 2015, at 47 N.J.R. 2736(a).

Adopted: February 29, 2016, by the **Division of Consumer Affairs,** Steve C. Lee, Acting Director.

Filed: August 25, 2016, as R.2016 d.117, with **non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-45 et seq. (P.L. 2007, c. 244, as amended by P.L. 2015, c. 74).

Effective Date: November 7, 2016.

Expiration Date: December 14, 2018.

Summary of Public Comments and Agency Reponses:

The official comment period ended January 15, 2016. The **Division of Consumer Affairs** (Division) received comments from:

1. Arthur Meisel, Executive Director, New Jersey Dental Association;

2. Mark Reiter, MD, MBA, FAAEM, President, American Academy of Emergency Medicine;

3. Philip Tsai;

4. Michael Marchetti, M.D.,

5. Doctor Katz;

6. Dyanne Westerberg;

7. Joshua Kaplan, M.D., New Jersey Medical School;

8. Dr. Rick Ludwin;

9. Allen Glushakow;

10. John C Kulin, D.O., FACEP, CEO, Urgent Care Now;

11. Anastasia Kunac, M.D., F.A.C.S., Assistant Professor of Surgery, Division Trauma Surgery and Surgical Critical Care, Rutgers-New Jersey Medical School;

12. Dr. Sinha Me;

13. Maher Ibrahim, M.D., Director, Interventional Pain Management Associates;

14. Caren Marks, M.D.,

15. Ira Port;

16. Evan Leibowitz;

17. David J. D'Apolito, DMD;

18. Teja Patel, DMD;

19. Reva Kaufman;

20. A. Chinnici, M.D.,

21. David Kuo, M.D., FACP, Clinical Associate Professor, Sidney Kimmel Medical College at Thomas Jefferson University, Director of Ambulatory Medical Education, Internal Medicine Faculty Associates, Associate Program Director, Morristown Medical Center, Internal Medicine Residency;

22. M. Patricia Harris, M.D., Atlantic Health System, Morristown Medical Center;

23. James L. McCabe, M.D., AVP Informatics, Chief Medical Information Officer, Kennedy Health System;

24. Reuben I. Ash, M.D., Site Medical Director, Urgent Care Now NJ-Mannahawkin;

25. Scott Mankowitz, M.D.,

26. Karen Berger;

27. Steven Levine;

28. Joshua Schor, M.D., FACP, CMD, Medical Director, Daughters of Israel;

29. Kedar Gokhale, M.D., Bergen Medical Associates;

30. Mark Heiberger, DDS;

31. Karen Mijal Lotz;

32. Steven Rosenbaum, M.D., FAAEM;

33. Hinal Patel, Pharm. D., BCPS, Transitions of Care Pharmacist, Hunterdon Medical Center;

34. Mishael Azam, Esq., Chief Operating Officer and Senior Manager, Legislative Affairs, Medical Society of New Jersey;

35. Raj Dhadwal;

36. Alise Shaughnessy-Hanley, Legal and Compliance, Aureus Pharmacy;

37. K. Cahill, DNP, MS, APN-BC, Clinical Associate Professor, Rowan Medicine;

38. Leonard Lyon, M.D.,

39. Samantha Siegel, MSN, APN-C, OCN;

40. D. Bock;

41. Pat Miller, MA, Operations Director, Cancer Center at Saint Barnabas Medical Center;

42. Yingying Chen;

43. Daniel Kahn, M.D.,

44. Mark W. Beyer, D.O.,

45. J. Kelly;

46. Anita McNeill, Pharmacy Manager, Qualitas Pharmacy;

47. Dr. Logithya Subendra;

48. Rolando Mercado, PharmD, Clinical Pharmacy Manager, Trinitas Regional Medical Center;

49. Mitchell F. Reiter, M.D., President of the New Jersey Orthopaedic Society; and

50. Jonathan Winter, M.D., President, Dermatological Society of New Jersey.

1. COMMENT: Three commenters noted that the prescription monitoring program (PMP) website is very informative and useful. One of these commenters further stated that she agrees that physicians should preview the prescription monitoring information when seeing patients.

RESPONSE: The Division thanks the commenters for their support of the PMP.

2. COMMENT: One commenter inquired whether the mandated quarterly reviews were in effect as of November 1, 2015.

RESPONSE: On November 1, 2015, P.L. 2015, c. 74, codified as N.J.S.A. 45:1-44 et seq., the new law concerning the New Jersey Prescription Monitoring Program (NJPMP), including the mandatory quarterly reviews, became effective. The Division encourages practitioners to integrate the statute's requirements into their practices.

3. COMMENT: One commenter sought clarification whether the law is in effect or whether it is only a proposal. The commenter noted that information provided from Appriss states that

the law is effective as of November 1, 2015, however, the New Jersey **Division of Consumer Affairs** website lists this as a proposal from November 16, 2015, with a comment period until January 15, 2016.

RESPONSE: The new law concerning the NJPMP is not a proposal and became effective on November 1, 2015. In accordance with the law, the Division proposed rules on November 16, 2015, to implement provisions of the law and govern the NJPMP. Comments on the proposed rules were accepted by the Division until January 15, 2016. The Division encourages practitioners to integrate the statute's requirements into their practices. The Division anticipates that, at the time this adoption notice is published, those authorized to be designated as a delegate may register with the Division for access to the PMP. In addition, the Division notes that in September 2011, the PMP became operational and pharmacies have been and continue to be required to [page=2375] collect and electronically transmit data consistent with the proposed rules.

4. COMMENT: One commenter sought clarification as to when the requirements begin and what he must do in the office.

5. COMMENT: Three commenters sought clarification about the specific circumstances under which the PMP must be consulted.

RESPONSE TO COMMENT 4 AND 5: The new law concerning the NJPMP became effective on November 1, 2015. In accordance with N.J.A.C. 13:45A-35.9(a), practitioners are required to consult the PMP the first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient for acute or chronic pain. Practitioners are also required to access the prescription monitoring information on a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain.

The law and rules also set forth exceptions to the mandatory look-up requirements. The mandatory look-up requirements of subsection (a) do not apply to a veterinarian, a practitioner, or practitioner's agent administering methadone as interim treatment for a patient on a waiting list for admission to an authorized substance abuse treatment program, a practitioner directly administering CDS to a patient, a practitioner prescribing a CDS that is to be dispensed by an institutional pharmacy, or a practitioner prescribing a CDS to a patient under the care of a hospice. Nor do the mandatory look-up requirements apply to a practitioner prescribing a CDS in an emergency department, if the prescription is for less than a five-day supply of the substance. If there is a situation in which it is not reasonably possible for the practitioner or pharmacist to access the PMP in a timely manner, no other individual authorized to access the PMP is reasonably available, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance, the mandatory look-up requirements do not apply. In addition, the mandatory look-up requirements do not apply in a situation under which consultation of the PMP would result in a patient's inability to obtain a prescription in a timely manner, thereby, in the clinical judgment of the practitioner or pharmacist, adversely impacting the medical condition of the patient. In such a situation, the quantity of CDS prescribed or dispensed cannot exceed a five-day supply of the substance. There is also an exception when the PMP is not operational as determined by the Division or where it cannot be accessed by the practitioner or the pharmacist due to a temporary technological or electrical failure, provided that the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance. The mandatory look-up requirements also do not apply when a practitioner is prescribing less than a 30-day supply of a CDS to a patient immediately, but no more than 24 hours, after the patient has undergone an operation, procedure, or treatment for acute trauma, for which a CDS is

recognized in the customary treatment of pain following such operation, procedure, or acute trauma. For purposes of this exception, a "procedure" is defined as an invasive procedure that requires anesthesia. The law and rules allow a practitioner to designate, as a delegate, a licensed health care professional or a certified medical assistant who is employed at the practice setting at which the practitioner practices. In addition, a practitioner must comply with the recordkeeping requirements set forth in N.J.A.C. 13:45A-35.10. If a practitioner designates a delegate, there are additional requirements set forth at N.J.A.C. 13:45A-35.8 and 35.10 with which the practitioner must comply.

6. COMMENT: One commenter requested to see the "specific circumstances" under which the doctor would have to check the PMP before dispensing. The commenter believes that the mandatory look-up requirements are not necessary for doctors prescribing for hospice patients, and would be very taxing on pain management doctors overall. The commenter would like to see all new patients presenting to a medical doctor's office for pain be researched before prescribing controlled medications.

RESPONSE: The specific circumstances under which a practitioner is required to check the PMP before prescribing a Schedule II controlled dangerous substance and the exceptions to the mandatory look-up requirements are explained in the Response to Comments 4 and 5. The Division notes that the law and rules provide an exception to the mandatory look-up requirements when a practitioner is prescribing a CDS to a patient under the care of a hospice.

7. COMMENT: One commenter asked whether prescribers are mandated to check the PMP at the time a Schedule II is prescribed and quarterly thereafter.

RESPONSE: Yes, prescribers are mandated to check the PMP the first time the practitioner prescribes a Schedule II for acute or chronic pain and quarterly thereafter, unless one of the exceptions set forth in N.J.A.C. 13:45A-35.9(c) applies. For the exceptions to the mandatory look-up requirements, see the Response to Comments 4 and 5.

8. COMMENT: One commenter inquired whether the PMP must be reviewed for every/any Schedule II medication or for only acute/chronic pain medications.

RESPONSE: Practitioners are required to consult the PMP the first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient for acute or chronic pain. In addition, practitioners are required to access the prescription monitoring information on a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain. In accordance with N.J.S.A. 45:1-46.1, N.J.A.C. 13:45A-35.9 provides exceptions to the mandatory look-up requirements. For the exceptions to the mandatory look-up requirements, see the Response to Comments 4 and 5 above.

9. COMMENT: One commenter asked whether the rule applies to hospitalists when they are discharging patients home with Schedule II controlled substances.

RESPONSE: The rules apply to hospitalists, unless one of the exceptions to the mandatory look-up requirements, as set forth in N.J.A.C. 13:45A-35.9(c), applies. For example, the mandatory look-up requirements will not apply if the hospitalist is a practitioner prescribing a CDS in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a five-day supply of the substance. Also, if the hospitalist is a practitioner who is prescribing less than a 30-day supply within 24 hours after the patient has undergone an operation, procedure, or treatment for acute trauma for which a CDS is

recognized in the customary treatment of pain following such operation procedure, or acute trauma. "Procedure" means an invasive procedure requiring anesthesia.

10. COMMENT: One commenter inquired whether the new law includes the oncology population and noted that some states do not require the mandatory look-up be adhered to for their oncology population.

RESPONSE: The law concerning the NJPMP created an exemption from the mandatory look-up requirements for those patients that are under the care of a hospice. The law did not include an exception from the mandatory look-up requirements for all oncology patients.

11. COMMENT: One commenter stated that the rule should allow patients who use narcotics and who are well-known to the doctor to be prescribed narcotics without the report being run.

RESPONSE: The law concerning the NJPMP requires practitioners to look up their patients in the prescription monitoring database to alert practitioners to potential risks of diversion and/or drug abuse. By reviewing the prescription monitoring information, practitioners are able to learn whether their patients are being prescribed CDS from other practitioners and whether their patients are complying with the practitioners' treatment regimens. The database enables prescribers to make treatment decisions that meet the best interests of patients.

12. COMMENT: One commenter inquired whether, as a semi-retired physician who sees 10 to 15 outpatients each week, does not take care of hospitalized patients, does not have internet access in his office, and was granted a hardship exemption from the electronic health record requirement by the Centers for Medicare & Medicaid Services for 2013 and 2014, he would be able to continue to prescribe controlled substances if he does not have access to the PMP and is unable to acquire the required information before he writes a prescription.

RESPONSE: Practitioners in these circumstances would not be able to write a prescription for a Schedule II controlled substance for acute or chronic pain. In accordance with N.J.A.C. 13:45A-35.9(a), practitioners are required to consult the PMP the first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient [page=2376] for acute or chronic pain. In addition, practitioners are required to access the prescription monitoring information on a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain. Practitioners may access the PMP through a mobile application, which is available for download for Apple iOS, Android, and Windows phone users.

13. COMMENT: One commenter asked whether she is allowed to write narcotic prescriptions if she has not done the training and does not have access to the NJPMP.

RESPONSE: Persons who do not complete the required online tutorial would not be able to register with the Division to access the PMP and would not be allowed to write prescriptions for Schedule II controlled dangerous substances for acute or chronic pain. All practitioners who are authorized to have online access to PMP information are required to register with the Division.

14. COMMENT: One commenter inquired whether an out-of-State pharmacy that dispenses controlled substance prescriptions to residents of long-term care facilities who are under 24-hour-nurse surveillance would be required to submit controlled substance prescription data

to the PMP. The commenter further inquired whether such a pharmacy would be eligible for a waiver of the PMP reporting requirement.

RESPONSE: In accordance with N.J.A.C. 13:45A-35.4, a registered pharmacy that dispenses Schedule II, III, IV, or V controlled dangerous substances or human growth hormone to only inpatients in a hospital, long-term, or other facility in which the residents are provided with 24-hour nursing care, are required to apply to the Division for an exemption from the PMP. Forms for requesting an exemption are available at http://www.nj.gov/lps/ca2/pmp/ExemptionWaiverApplication.pdf.

15. COMMENT: One commenter sought clarification about the application of the new law to out-of-State pharmacists and how a non-resident pharmacy registered with the State sets up a PMP account for a pharmacist-in-charge who does not hold a New Jersey license. The commenter noted that in such a circumstance it is interested in being able to check a patient's PMP record before dispensing a controlled substance in order to comply with the new law.

RESPONSE: To register with New Jersey's Prescription Monitoring Program, persons who are authorized to have access to the PMP must be licensed by the State of New Jersey and in good standing with their respective licensing boards. An out-of-State pharmacy has access to the prescription monitoring program of the state in which it resides and may, through the state's interoperability agreement, access information available in the NJPMP. The Division continues to strive to have interoperability agreements with all states to facilitate sharing information. But currently, there may be circumstances under which a pharmacist working for an out-of-State pharmacy does not have access to New Jersey's PMP information.

16. COMMENT: One commenter noted that the proposed regulations require prescribers to review the prescription monitoring information for both "new" or "current" patients, however, the statute appears to require a review for only new patients. The commenter stated that N.J.S.A. 45:1-46.1 makes a clear differentiation between "new patients" and "current patients" and that the statute does not direct a practitioner to access the PMP when a Schedule II controlled dangerous substance is prescribed to a "current," as distinguished from a "new," patient. The commenter further stated that the statute requires access for a current patient on only a quarterly basis.

RESPONSE: As all current patients who are prescribed a Schedule II controlled dangerous substance for acute or chronic pain are subject to the quarterly look-up requirement, there must be an established time for which the look-up begins for current patients. Accordingly, on or after November 1, 2015 (the effective date of the law), the first time a practitioner writes a prescription for a Schedule II controlled dangerous substance the practitioner must consult the PMP for current and new patients, and quarterly thereafter.

17. COMMENT: One commenter raised a concern with proposed N.J.A.C. 13:45A-35.9(c)11i, which states that "[f]or purposes of this paragraph, 'procedure' means an invasive procedure that requires anesthesia." The commenter noted that certain invasive procedures may not always require anesthesia but still require opioid prescriptions, for example, a fracture reduction. The commenter requested that the rule be modified to add the word "may" such that the rule would read, "[f]or purposes of this paragraph, 'procedure' means an invasive procedure that may require anesthesia."

RESPONSE: The Division declines to amend the rule as suggested by the commenter. The Division believes it is reasonable to narrowly view the exemption set forth in N.J.A.C. 13:45A-35.9(c)11 because of the sizeable quantity of Schedule II CDS that a practitioner

may prescribe to a patient without consulting the PMP.

18. COMMENT: Three commenters requested that the Division remove the audit requirement in N.J.A.C. 13:45A-35.8(e)3. The commenters believe that this is a very onerous, time-consuming, and unfunded mandate that will greatly dissuade practitioners from delegating their authority and mandatory duty to check the PMP in order for physicians to help reduce diversion. The commenters also believe that the requirement creates mistrust between the physician and the delegate, and that delegates are health professionals who are already subject to State and Federal laws that protect patient privacy, and are trusted team members, employees, and care providers. The commenters further stated that the audit requirement creates an unnecessary administrative burden, and fails to recognize that a delegate is already providing patient care and already trusted with patient information. The commenters also stated that the concern for misuse of PMP information should not outweigh the shared desire to improve the program and reduce diversion. The commenters believe that the audit requirement severely goes against the improvements to the PMP made under P.L. 2015, c. 74, and physicians should have discretion on how to monitor the conduct and practices of their employees. The commenters believe that the six-month period audit may not be the most effective way for a physician to balance patient information protection with the provision of quality care and reduction of abuse or diversion.

RESPONSE: The Division disagrees that the audit requirement is onerous or time-consuming. Through the PMP, practitioners are able to run reports showing the look-up history of their delegates, which practitioners can cross-reference with the names of their patients. The rules permit practitioners to designate an unlimited number of delegates to access the PMP on the practitioners' behalf. In accordance with N.J.S.A. 45:1-45, the Division is required to minimize the burden to practitioners to the extent practicable while protecting the confidentiality of the prescription monitoring information obtained. The law also establishes that practitioners are responsible for the use or misuse of the prescription monitoring information by their delegates. The bi-annual audit of the delegate's use of the PMP provides an effective mechanism for practitioners to ensure that their delegates are complying with the law and rules.

19. COMMENT: One commenter stated that, as a general rule, dentists do not conduct "audits" and, absent clarification, would not know how to proceed. The commenter suggested that, if the audit requirement remains in the regulation, the Division either should issue a check-list or a detailed description of the audit process or, in lieu of the audit, consider a written statement by the authorized delegate certifying that there has been no misuse of the PMP or prescription monitoring information. In addition, the commenter suggested that the Division consider eliminating the proposed audit requirement because persons who can be authorized by dentists to access the PMP are subject to direct oversight by the Board of Dentistry.

RESPONSE: The Division declines to eliminate the bi-annual audit requirement as it is an effective mechanism for practitioners to ensure that their delegates are complying with the law and rules. The law establishes that practitioners are responsible for the use or misuse of the prescription monitoring information by their delegates. Through the PMP, dentists are able to run reports showing the look-up history of their delegates, which can be cross-referenced with the names of their patients. The Division believes that the dentists, and other practitioners, are in the best position to identify inappropriate and unauthorized access to the PMP.

20. COMMENT: Three commenters sought clarification that the Division will provide forms

and guidance to physicians and other prescribers to help them comply with the requirements of N.J.A.C. 13:45A-35.8(d). Specifically, the commenters requested that the [page=2377] Division provide forms to practitioners that provide written instructions to help them comply with the requirements to "ensure that the delegate understands the limitation on disclosure" in paragraph (d)1, and to "confirm" the education criteria for certified medical assistants in paragraph (d)2. The commenters stated that, if a form is provided, it will help the practitioners comply with the requirement and lessen liability fears. In addition, the commenters stated that delegation was included in the legislation to enable physicians to use the PMP more efficiently, thus facilitating greater participation. The commenters believe that the creation of administrative burdens around delegation goes against the spirit of the legislation and will discourage physicians from such delegation. The commenters further noted that delegates are health professionals who are already subject to State and Federal laws that protect patient privacy, including the Federal Health Insurance Portability and Accountability Act of 1996.

RESPONSE: The Division will endeavor to work with, and make resources available to, the respective licensing boards and professional associations to assist practitioners with their responsibility to ensure that their delegates understand the limitation on disclosure of the prescription monitoring information, and the Federal and State laws, rules, and regulations concerning the confidentiality of patient information. In addition, the Division will endeavor to work with the respective licensing boards and professional associations to create a checklist of the education criteria for certified medical assistants consistent with the qualifications set forth in N.J.A.C. 13:45A-35.2.

21. COMMENT: One commenter noted that, recognizing the practical difficulty and disruption of patient care that could result in a dental office by limiting access to the PMP solely to licensed dentists, access was extended to authorized licensed dental hygienists and registered dental assistants. The commenter further noted that access was restricted solely to those two categories of dental auxiliary personnel because they are subject to the regulatory and disciplinary oversight of the Board of Dentistry. In addition, the commenter believes that, in the event a licensed dental hygienist or a registered dental assistant violates the PMP without a dentist's knowledge or approbation and contrary to the dentist's specific instructions, it would be fundamentally unfair to subject the dentist to disciplinary action for the unauthorized use or misuse of information. To avoid a chilling effect in the use of delegates, the commenter urges the Division to clarify that a dentist will not be subject to discipline for the unilateral unauthorized violations by auxiliary personnel.

RESPONSE: The Division believes that the dentists, and other practitioners, are in the best position to identify inappropriate and unauthorized access to the PMP. The Division will consider the fact-specific circumstances of each incident and the degree of responsibility demonstrated by each practitioner with respect to any discovered or suspected violations, including but not limited to, reporting such information to the Division and/or respective licensing board; educating his or her delegates; and complying with the periodic audit requirement.

22. COMMENT: One commenter stated that as an emergency physician it would be extremely burdensome to use the prescription monitoring program for all patients who needed controlled medications. The commenter noted that emergency physicians do not have the time to look up every patient and some people needing medications will not receive them if the physicians have to go through this process on everyone. The commenter further stated that emergency physicians have become very astute at "weeding these people [narcotic seekers] out" and the choice should be left to them to decide who needs to be looked up. The commenter requested that emergency physicians be exempt from the

mandatory look-up requirement as it will be bad for patient care.

23. COMMENT: One commenter suggested that urgent care centers be included in the exception to the mandatory look-up requirements. The commenter noted that, just as in emergency rooms, urgent care centers often have episodic visits that require urgent attention, as well as a high-volume of patients during the course of the day from 60 to 110 visits during a 10-hour period. The commenter further noted that to access the PMP information for each patient is quite troublesome, effecting quality, timely evaluations and treatments, and is disruptive to the follow-up of care in urgent care centers.

24. COMMENT: One commenter requested an exemption from the rules for all emergency and urgent care physicians. The commenter believes it is critically important that the implementation of the new law recognize the unique and distinct nature of emergency medicine, which focuses on the management of acute injury and illness, versus the management of chronic pain, which typically occurs in outpatient settings. The commenter supports the expansion of, and physician access to, prescription drug monitoring programs, however, the commenter is concerned about a broad-based mandate whereby it "must be utilized in all cases of narcotic prescriptions that are being written," which fails to recognize the diversity and homogeneity of healthcare settings in New Jersey. The commenter further stated that the new law is unnecessary for those many patients with true acute/emergent pain (such as fractures, motor vehicle collisions, or cancer) and will delay the physicians striving to provide timely quality care in busy emergency departments. The commenter believes that spending extra time accessing a database at a computer will certainly delay patient care, and potentially of critically ill patients. The commenter also believes that providers should access a prescription drug monitoring program when it is deemed necessary by the treating physician, but not as a mandatory requirement.

25. COMMENT: One commenter noted that there has been an epidemic of narcotic abuse not only in New Jersey but the entire country, death rates from this type of abuse have skyrocketed, and the problems have been getting worse over the years. The commenter stated that he agrees that it is important to give physicians the opportunity to be able to check a database with regard to frequent narcotic/opioid prescription abuse. The commenter, however, believes that in a medical environment, such as an emergency department or urgent care center where physicians frequently treat patients with acute fractures, cancer, post-operative complications causing pain, and other medical issues that, irrespective of the findings in a database, absolutely and clearly require strong pain medications such as Schedule II medications, mandating that emergency room and urgent care physicians take time away from patient care to check a database when a patient will require strong pain medication is not in the best interests of the physician, the patient(s), or the facility where the physician is working. The commenter noted that physicians are pressured to see patients more and more rapidly while still providing excellent care to patients, while emergency care censuses continue to rise year after year. In addition, the commenter noted that not all emergency departments and urgent cares have nurse practitioners, physician assistants, or assistants who can check the PMP database on behalf of the physician, and the responsibility will then fall to the physician to take the time away from patient care to do so, which will then impede the provision of "rapid" quality care. The commenter stated that there are numerous patients every single day that every physician in these settings cares for and no matter what a database shows, will require narcotic prescriptions, and that emergency and urgent care physicians frequently treat patients with acute injuries and illnesses requiring acute pain management upon discharge from their facility. The commenter believes that it would be inappropriate and extraordinarily burdensome to the practicing emergency department/urgent care physician to have to check a database every single time a patient with a fracture or any of the other many

injuries and illnesses that clearly require strong pain medication for treatment, present for care. The commenter urged the Division to carve out the emergency department and urgent cares from this law so they are not required to comply with this otherwise helpful law. In addition, the commenter believes that the law should clearly delineate conditions where emergency and urgent care physicians can treat patients appropriately with narcotics/opioids without having to consult a database.

RESPONSE TO COMMENTS 22, 23, 24, AND 25: In accordance with N.J.S.A. 45:1-46.1, N.J.A.C. 13:45A-35.9(c)5 provides that a practitioner prescribing a CDS in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a five-day supply of the substance, is exempt from the mandatory look-up requirements. In addition, the mandatory look-up requirement does not apply when a practitioner is administering a CDS directly to a patient, or the CDS is dispensed by an institutional pharmacy. The mandatory look-up requirements also do not apply when a practitioner is prescribing less than a 30-day supply of a CDS to a patient immediately, but no more [page=2378] than 24 hours, after the patient has undergone an operation, procedure, or treatment for acute trauma, for which a CDS is recognized in the customary treatment of pain following such operation, procedure, or acute trauma. For purposes of the exception to the mandatory look-up requirements, a "procedure" is defined as an invasive procedure which requires anesthesia.

The exemptions to the mandatory look-up requirements, which are established by law (N.J.S.A. 45:1-46.1(b)), do not specify urgent care centers or physicians providing care at such centers. The Division notes that, to lessen the burden on a practitioner's time, the law and rules allow urgent care physicians to designate delegates to look up a patient's prescription monitoring information.

26. COMMENT: One commenter suggested expanding the exceptions to the mandatory look-up requirement set forth in N.J.A.C. 13:45A-35.9(c)11 to include acute medical conditions that involve moderate to severe pain but are not related to trauma or a procedure, such as kidney stones, gall stones, pleurisy, radiculopathies, and neuralgias. The commenter noted that patients are seen in the emergency department every day with non-traumatic conditions, many of whom require a short course of opioid analgesia, and having to look up each patient in the PMP can create delays in emergency department throughput.

RESPONSE: The law does not provide an exemption from the mandatory look-up requirement for acute medical conditions that involve moderate to severe pain but are not related to an operation, procedure, or acute trauma. The Division notes that, to lessen the burden on a practitioner's time, the law and rules allow emergency room physicians to designate delegates to look up a patient's prescription monitoring information. See also the Response to Comments 22, 23, 24, and 25.

27. COMMENT: One commenter requested including urgent care centers in the section that does not require a mandatory look-up for less than a five-day supply. The commenter noted that most urgent care centers limit the prescribing of controlled dangerous substances to five days maximum and see patients with trauma that sometimes requires a CDS prescription for an acute painful injury.

RESPONSE: The law establishes the exemptions to the mandatory look-up requirements. The exemption at N.J.A.C. 13:45A-35.11(c)5, as set forth in the statute at N.J.S.A. 45:1-46.1(b)5, is limited to the practitioner in the emergency department of a general hospital and does not include urgent care centers.

28. COMMENT: One commenter recommended expanding the exceptions to the mandatory look-up requirement to include those who practice in nursing homes, skilled nursing facilities, and assisted living facilities because they serve a population with high levels of chronic pain and the risk of diversion seems very low in this setting and population. The commenter applauds the goals of reducing diversion but has seen in New York that this type of regulation resulted in an alarming retreat from pain treatment of the frail elderly in nursing homes. The commenter expressed concern that frail elderly people in true chronic pain from arthritis, malignancy, spinal conditions, etc., will be under-treated. The commenter noted that there has been much progress in recognizing pain as a "vital sign" and going along with various campaigns to properly and adequately treat these people with sometime strong pain medications, which are in fact safer in the frail elderly than NASAID (non-steroidal or anti-inflammatory drugs) medications, and stated that he would not want see this rolled back in any way.

RESPONSE: The exemptions to the mandatory look-up requirements are established by law. N.J.S.A. 45:1-46.1 does not include an exemption for those who practice in nursing homes, skilled nursing facilities, and assisted living facilities. The Division notes that the law and proposed rules do not restrict a practitioner's ability to prescribe or properly treat patients with legitimate medical problems.

29. COMMENT: Three commenters inquired about whether staff (receptionist, dental assistant, officer manager) could access the PMP on the doctor's behalf to check the patient's PMP profile. One of these commenters noted that in a busy primary care practice it is very difficult to regularly check the prescription monitoring program and it would be nice if the office staff could assist by accessing the program. Another commenter noted that given the real imperative for efficiency within medical practices, it would be important for qualified support staff within a given practice to have access to the prescription monitoring information. This commenter noted, for example, that many practices rely on their nurses or certified medical assistants to pre-load or enter preventive health data, lab orders, and prescription information into electronic records so these might simply be "reviewed and approved" by the attending physician. In addition, the documentation requirement for patient encounters, partly as a result of the Affordable Care Act, has increased, therefore, staff support is necessary for physicians to see patients within a reasonable amount of time. The commenter believes that enabling qualified support staff to "cue up" prescription monitoring reports in advance of or during a visit will enable physicians to spend more time directly with patients during encounters.

RESPONSE: In accordance with N.J.S.A. 45:1-46, N.J.A.C. 13:45A-35.8 provides that delegates may be designated to access PMP information. Practitioners may designate a delegate who is a licensed health care professional or a certified medical assistant who is employed at the practice setting at which the practitioner practices. A licensed dentist may designate a delegate who is a registered dental assistant employed at the practice setting at which the licensed dentist practices dentistry. Pursuant to N.J.A.C. 13:45A-35.2, a "licensed health care professional" is defined as a registered nurse, licensed practical nurse, or dental hygienist licensed pursuant to Title 45 of the Revised Statutes. A "licensed health care professional" also means an advanced practice nurse or a physician assistant who accesses the PMP as a delegate. A "certified medical assistant" is a person who is a graduate of a post-secondary medical assisting educational program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), or its successor, the Accrediting Bureau of Health Education Schools (ABHES), or its successor, or any accrediting agency recognized by the U.S. Department of Education, which educational program includes, at a minimum, 600 clock-hours of instruction, and encompasses training in the administration of intramuscular and subcutaneous injections, as well as instruction

and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique, including sterile technique; hazards and complications; and emergency procedures; and who maintains current certification or registration, as appropriate, from the Certifying Board of the American Association of Medical Assistants (AAMA), the National Center for Competency Testing (NCCT), the American Medical Technologists (AMT), or any other recognized certifying body approved by the Board of Medical Examiners.

30. COMMENT: One commenter suggested expanding N.J.A.C. 13:45A-35.1 and 35.2 to allow pharmacy technicians to have PMP access.

RESPONSE: The law establishes the persons who are required to and may have access to the PMP. Pursuant to N.J.S.A. 45:1-46, pharmacy technicians are not authorized to have access to the PMP and may not be designated as a delegate.

31. COMMENT: One commenter requested the status of office staff helping the physicians implement the mandatory look-up requirement.

RESPONSE: The Division has been implementing the technology needed to allow delegates to access the PMP. The Division anticipates that, at the time this notice of adoption is published, those authorized to be designated as a delegate may register with the Division and receive access to the PMP.

32. COMMENT: One commenter noted that the prescription monitoring program needs to be made more user-friendly because currently it is very slow and awkward to use.

RESPONSE: The Division continues to assess the technological capabilities of the PMP and strives to take advantage of new technologies as they develop.

33. COMMENT: One commenter noted that it would be helpful to have a smartphone app that allowed doctors to check the database when they are away from their office.

RESPONSE: There is a mobile application available for accessing the PMP for Apple iOS, Android, and Windows phone users. It is available for download from the respective app stores of each manufacturer. The Division notes that the Windows version will only work on a mobile [page=2379] phone. The mobile application uses the same user name and password that a person uses to log-in to the PMP website and the application has the same patient search functionality as the website.

34. COMMENT: One commenter suggested that the New Jersey Prescription Monitoring service be easier to log into and noted that the requirements for the password are too stringent. The commenter also inquired whether there is a way to remain logged into the program using a smart phone.

RESPONSE: To protect patient information, which is confidential and private, the Division declines to ease the password requirements or the program's automatic time-out settings.

35. COMMENT: Two commenters requested allowing the PMP database to interface with electronic medical records (EMRs), as it will save time and encourage use of the PMP, which will ensure compliance. One of the commenters noted that the PMP site's accessibility has been an issue since its inception because of the inability to access the PMP site through the EMR.

RESPONSE: The PMP currently has the capacity to interface with electronic medical records. The Division notes that EMRs are operated by private sector companies and it is within the purview of their individual business model whether to establish an interface with the PMP.

36. COMMENT: One commenter inquired as to the ability to develop an application programming interface (API) for automatically downloading the PMP reports through the EMR. The commenter suggested that this would allow, by using the provider's credentials and all available patient information, for an automated request to be sent to the PMP as soon as a patient registers to be seen in the clinic, emergency room, hospital, office, and, if there is a report, for it to be pre-downloaded, so that the provider can review it before creating new prescriptions.

RESPONSE: The PMP has the API, which would allow the PMP to interface with electronic medical records. The Division notes that EMRs are operated by private sector companies and it is within the purview of their individual business model whether to establish an interface with the PMP.

37. COMMENT: One commenter suggested including the phone and fax number for each prescriber the patient has visited so the prescription monitoring information can be shared to get the patient help to reach for recovery.

RESPONSE: Assuming the accuracy and completeness of the information inputted into the PMP, practitioners should have the contact information for each prescriber from whom the patient was prescribed a controlled dangerous substance.

38. COMMENT: One commenter suggested that it would be beneficial to incorporate into the database the diagnosis of those patients requiring scheduled narcotics to identify the terminally ill or oncology patients. The commenter noted that there are terminally ill patients either in hospice or currently receiving chemotherapy and/or radiation who are legitimately in severe pain from malignancies.

RESPONSE: The PMP does not have fields to include diagnoses. In accordance with the law, N.J.A.C. 13:45A-35.9(c)6 provides an exception from the mandatory look-up requirements for those patients under the care of a hospice. The Division notes that the law and proposed rules do not restrict a practitioner's ability to prescribe or properly treat patients with legitimate medical problems.

39. COMMENT: One commenter inquired whether printing a patient profile from the PMP and scanning it into the patient's EMR record is a violation of the law.

RESPONSE: It is not a violation of law to print a patient profile from the PMP and scan it into the patient's EMR record.

40. COMMENT: One commenter noted that the proposal is very unwieldly, needlessly complicated, and time-consuming.

RESPONSE: The Division notes that the notice of proposal comports with the requirements of the Administrative Procedures Act, set forth at N.J.S.A. 52:14B-1 et seq., as well as the Rules for Agency Rulemaking, N.J.A.C. 1:30, promulgated by the Office of Administrative Law, which are intended to provide notice to interested parties about new regulatory requirements. The proposed rules implement the law requiring practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain. The PMP provides patient information that is intended to supplement an evaluation of

a patient, confirm a patient's drug history, or document compliance with a therapeutic regimen. Using this information and the practitioner's professional judgment will help the fight against drug abuse and diversion. In addition, this information enables the prescriber to select treatment options that are in the best interests of the patient.

41. COMMENT: One commenter stated that the regulation to consult with another bureaucrat concerning dispensing Schedule II drugs is burdensome, will prevent good doctors from properly treating patients with legitimate medical problems, and will result in delays.

RESPONSE: The law requires practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain to a patient for the first time and on a quarterly basis thereafter. The PMP is a database of prescription medications filled by a pharmacy for New Jersey patients. It does not restrict a practitioner's ability to prescribe or properly treat patients with legitimate medical problems. The PMP provides patient information that is intended to supplement an evaluation of a patient, confirm a patient's drug history, or document compliance with a therapeutic regimen. Using this information and the practitioner's professional judgment will help the fight against drug abuse and diversion. In addition, this information enables the prescriber to select treatment options that are in the best interests of the patient. The Division notes that, to lessen the burden on a practitioner's time, the law and rules allow practitioners to designate delegates to look up a patient's prescription monitoring information.

42. COMMENT: One commenter noted that physician time with patients is becoming more restricted, and adding an additional requirement that mandates consultation of the NJPMP prior to writing prescriptions for every patient takes time away from the patients during a patient visit. The commenter contended that of all of those who are prescribed Schedule II medications, only a fraction abuse them. The commenter suggested instead, that the system be designed to notify physicians when a threshold level of prescriptions has been released (especially when prescribed by multiple different providers). The commenter stated that the notifications could be automated and sent via e-mail and, at that point, the physician could be held accountable for addressing the issue in the context of a patient visit. The commenter believes that this is a far more reasonable way to combat the problem of prescription drug abuse and believes that compliance with the law will be poor.

RESPONSE: This approach cannot be taken because the Division's proposed rules implement the requirements of the new law that requires practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain. Practitioners are required to consult the PMP the first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient for acute or chronic pain. In addition, practitioners are required to access the prescription monitoring information on a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain. The law and rules allow practitioners to designate delegates to lessen the burden on a practitioner's time. The Division believes that the rules balance protecting patients and the public by fighting drug diversion and abuse, with minimal burden to the practitioners.

43. COMMENT: One commenter noted that checking the prescription monitoring program each time a prescriber writes a prescription for a controlled medicine will delay post-surgery patients from getting pain medicine and it will slow down overall work flow in the doctor's office.

RESPONSE: In accordance with N.J.S.A. 45:1-46.1(b), N.J.A.C. 13:45A-35.9(c) provides an

exception to the mandatory look-up requirements for a practitioner directly administering CDS to a patient. The mandatory look-up requirements also do not apply when a practitioner is prescribing less than a 30-day supply of a CDS to a patient immediately, but no more than 24 hours, after the patient has undergone an operation, procedure, or treatment for acute trauma, for which a CDS is recognized in the customary treatment of pain following such operation, procedure, or acute trauma. The Division notes that, to lessen the burden on a practitioner's time, the law and rules allow [page=2380] practitioners to designate delegates to look up a patient's prescription monitoring information.

44. COMMENT: One commenter noted that the mandatory look-up requirement will be extremely onerous in a busy office setting. The commenter suggested that the look-up should be done by information given from either the pharmacy or the electronic clearinghouse.

RESPONSE: This suggested approach cannot be implemented because the law requires practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain to a patient for the first time and on a quarterly basis thereafter. The PMP provides patient information that is intended to supplement an evaluation of a patient, confirm a patient's drug history, or document compliance with a therapeutic regimen. Using this information and the practitioner's professional judgment will help the fight against drug abuse and diversion. To lessen the burden on a practitioner's time, the law and rules allow practitioners to designate delegates to look up a patient's prescription monitoring information. The Division believes that the rules balance protecting patients and the public by fighting drug diversion and abuse, with minimal burden to the practitioners.

45. COMMENT: One commenter suggested changing the interval required to check the PMP for Schedule II prescriptions from every three to six months. The commenter noted that, although checking the PMP is not difficult, it will add to the already large amount of time required to properly care for rheumatoid patients, which includes ensuring they adhere to their pain contract, performing random urine toxicology screening, and keeping up with writing and documenting monthly refills. The commenter suggested that the PMP send to prescribers reminder emails every three months for each of the prescriber's patients that require review because, given how busy clinicians are, it will be challenging to remember to check every three months on all of the Schedule II patients.

RESPONSE: The law requires practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain to a patient for the first time and on a quarterly basis thereafter. To comply with the quarterly review requirement, practitioners may designate delegates to access their patient's prescription monitoring information. In addition, practitioners can establish protocols that they deem necessary to let them or their delegates know when to conduct the quarterly review as required under the law.

46. COMMENT: One commenter raised concerns about a legislative solution to a problem that cannot be legislated. The commenter noted that Monmouth County and Ocean County have very high rates of death from heroin overdose because obtaining prescription medication is getting harder. Instead of going to a neighborhood pharmacy to obtain drugs, people are buying heroin on the street in some back alley. The commenter stated that the chance of overdose from intravenous use of narcotic (and higher chance for disease transmission) is much greater than buying and taking a pill. The commenter believes that, although you can overdose using pills, it takes a lot more of them and you are more likely

to throw up than stop breathing with the injectable narcotics. The commenter also believes that trying to legislate a solution to one problem, will create a more serious problem because people who are addicted to drugs will always find a way to get high and will always be one step ahead of the law. The commenter further questioned why the law clamps down on prescription drug subscribers but legalizes marijuana and suggested that in time marijuana usage is going to lead to the need for harder drugs as people become more tolerant and seek a new high.

RESPONSE: The Legislature determined that the PMP is a useful tool in combatting the opioid abuse epidemic in the State. The Division believes that using the prescription monitoring information and the practitioner's professional judgment will help the fight against drug abuse and diversion.

47. COMMENT: One commenter inquired whether the prescriber should deny a patient pain medication if the patient appears in the database, and whether prescribers have to check the database for every patient.

RESPONSE: The law requires practitioners to consult the PMP before prescribing a Schedule II controlled dangerous substance for acute or chronic pain to a patient for the first time and on a quarterly basis thereafter. It does not restrict a practitioner's ability to prescribe or to properly treat patients with legitimate medical problems. The PMP provides patient information that is intended to supplement an evaluation of a patient, confirm a patient's drug history, or document compliance with a therapeutic regimen. Using this information and the practitioner's professional judgment will help combat the opioid abuse epidemic in the State.

48. COMMENT: One commenter inquired as to the recourse a patient has if the information in the database is erroneous.

RESPONSE: The law provides that the Division shall establish a process for correcting information. The Division will promulgate rules for this process in a future rulemaking.

49. COMMENT: One commenter questioned whether the mandatory look-up requirement was a "new revenue generating scam" and inquired whether prescribers would have to pay a fee to see the database.

RESPONSE: The Legislature determined and the Division agrees that the PMP is a useful tool in combatting the opioid abuse epidemic in the State. There is no fee to register for or to access the PMP information.

50. COMMENT: One commenter believes that pharmacists should be responsible for checking the database and screening for abuse, as well as drug interactions. The commenter stated this would streamline the process as the final line of defense against abuse.

RESPONSE: The law establishes responsibilities for both prescribers and pharmacists, in recognition that healthcare practitioners must work together to combat the problems of drug abuse and diversion.

51. COMMENT: One commenter suggested requiring prescription blanks to include a raised stamp similar to a notary seal bearing the prescriber's name because the seal insures that if a blank prescription is stolen and forged, it will not be filled because it lacks the highly personalized stamp.

RESPONSE: The requirements for prescription blanks are established at N.J.A.C. 13:45A-27. The rules provide for existing security measures for the printing of prescription blanks. The Division intends to propose additional security measures for the paper itself in the future. A personalized stamp is not a recognized security measure.

52. COMMENT: One commenter suggested that when the prescriber looks up the patient in the PMP, the prescriber should receive an authorization code which would be put on the prescription blank. The commenter stated that the pharmacist would then have to enter the authorization code into the computer and the system would make sure it matches for any Schedule II.

RESPONSE: Prescribers who are concerned about altered prescription blanks are encouraged to electronically transmit prescriptions to pharmacies.

53. COMMENT: One commenter suggested sending a list of all medications requiring further evaluation prior to authorization or have a website for easy look-up.

RESPONSE: The Division will include on its website a link to the DEA website that contains the list of Schedule II controlled dangerous substances.

54. COMMENT: One commenter suggested having continuing education courses for practitioners as to what to do with the information obtained from the database.

RESPONSE: As issues and questions continue to be recognized, the Division believes that there will be additional opportunities for practitioners to avail themselves of continuing education courses identifying red flags and strategies that best meet the needs of their patients.

55. COMMENT: One commenter stated that doctors should also have the obligation to check for doctor shopping and misuse of controlled substances, and to pay the consequences if they do not review or disregard the prescription monitoring information. The commenter further stated that the doctors need to be held responsible for the controlled substances they prescribe.

RESPONSE: The Division notes that State and Federal law and rules impose corresponding responsibility on both the prescribers and the [page=2381] pharmacists to work together to address the scourge of drug diversion and abuse.

Summary of Agency-Initiated Changes:

The Division is changing N.J.A.C. 13:45A-35.8(c)1 and 2 to specify that once an individual's employment ends at the practice setting at which the delegating practitioner is practicing, the individual is no longer authorized to be a delegate or access the PMP on behalf of that practitioner. These changes do not require any additional public notice because it does not change the effect of this rule. One of the conditions to be designated as a delegate includes employment at the practice setting at which the practitioner practices.

The Division is changing N.J.A.C. 13:45A-35.9(c), to specify that the provisions of both subsections (a) and (b), as applicable do not apply. This change does not require any additional public notice because it does not change the effect of this rule. The regulated community and the public were on notice that the provisions of subsection (b) did not apply to the circumstances set forth in the applicable exemptions in subsection (c).

The Division is also changing N.J.A.C. 13:45A-35.11(f)1i to reflect that the authorized representative is for the patient. Additional public notice of this change is not required because it merely clarifies who the authorized representative is representing.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rules are governed by N.J.S.A. 45:1-44 et seq. (P.L. 2007, c. 244, as amended by P.L. 2015, c. 74). However, the adopted new rules require the Division, all pharmacies transmitting prescription drug information to the PMP, and all persons authorized to access PMP prescription drug information, to comply with the Federal Health Insurance Portability and Accountability Act of 1996, and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164. In addition, the Division notes that the adopted new rules requiring pharmacies to transmit information to the PMP about prescriptions dispensed for human growth hormone are consistent with the Federal definition of that term under the Federal Food, Drug, and Cosmetic Act at 21 U.S.C. § 333.

The Division believes that the adopted new rules are consistent with the standards established under the Federal National All Schedules Prescription Electronic Reporting Act of 2005, Pub.L. 109-60 (NASPER), which created a United States Department of Health and Human Services grant program for states to implement or enhance prescription drug monitoring programs.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***):

SUBCHAPTER 35. PRESCRIPTION MONITORING PROGRAM

13:45A-35.1 Purpose and scope

(a) The rules in this subchapter implement the provisions of P.L. 2007, c. 244, as amended by P.L. 2015, c. 74 (N.J.S.A. 45:1-44 through 51), establishing a Prescription Monitoring Program (PMP) in the **Division of Consumer Affairs.**

(b) The rules in this subchapter shall apply to the following:

1. A pharmacy filling prescriptions in New Jersey in an outpatient setting for a Schedule II, III, IV, or V controlled dangerous substance or for human growth hormone.

i. For purposes of this subchapter, "human growth hormone" means somatrem, somatropin, or any analogue of either of them, consistent with 21 U.S.C. § 333(e)4;

2. An out-of-State pharmacy registered with the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20 that ships, mails, distributes, or delivers a Schedule II, III, IV, or V controlled dangerous substance or human growth hormone into New Jersey in an outpatient setting pursuant to a prescription;

3. A person authorized to receive PMP information from the Division under N.J.S.A. 45:1-46 and N.J.A.C. 13:45A-35.6;

4. A pharmacist employed by a current pharmacy permit holder;

5. A practitioner who has a current State Controlled Dangerous Substance (CDS) registration;

6. A licensed health care professional authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

7. A medical resident authorized by a faculty member of a medical teaching facility to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

8. A dental resident authorized by a faculty member of a dental teaching facility to access the prescription monitoring information, subject to the limitations and requirements of this subchapter;

9. A certified medical assistant authorized by a practitioner to access the prescription monitoring information, subject to the limitations and requirements of this subchapter; and

10. A registered dental assistant authorized by a licensed dentist to access the prescription monitoring information, subject to the limitations and requirements of this subchapter.

(c) The reporting requirements of this subchapter shall not apply to the direct administration of a controlled dangerous substance or human growth hormone to the body of an ultimate user; or to the administration or dispensing of a controlled dangerous substance that is otherwise exempted as determined by the Secretary of Health and Human Services pursuant to the National All Schedules Prescription Electronic Reporting Act of 2005, Pub.L. 109-60.

(d) The reporting requirements of this subchapter shall not apply to any prescriptions filled by a pharmacy for a Schedule II, III, IV, or V controlled dangerous substance or for human growth hormone dispensed to an inpatient at a hospital, long-term care, or other facility in which the resident is provided with 24-hour nursing care.

13:45A-35.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise:

"Abuse" means a maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state (high), to sustain opioid dependence (that is opioid addiction), or that is other than the purpose for which the medication was prescribed.

"Acute pain" means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma, or disease and is generally persistent for up to one month, but no more than three months.

"Acute trauma" means serious illness and traumatic injuries requiring immediate short-term medical care to relieve suffering and minimize morbidity and mortality risk.

"CDS registration" means registration with the **Division of Consumer Affairs** to manufacture, distribute, dispense, or conduct research with controlled dangerous substances issued pursuant to P.L. 1970, c. 226 § 11 (N.J.S.A. 24:21-11).

"Certified medical assistant" means a person who is a graduate of a post-secondary medical assisting educational program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation (CAHEA), or its successor, the Accrediting Bureau of Health Education Schools (ABHES), or its successor, or any accrediting agency recognized by the U.S. Department of Education, which educational program includes, at a minimum, 600 clock-hours of instruction, and encompasses training in the administration of intramuscular and subcutaneous injections, as well as instruction and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique, including sterile technique; hazards and complications; and emergency procedures; and who maintains current certification or registration, as appropriate, from the Certifying Board of the American Association of Medical Assistants (AAMA), the National Center for Competency Testing (NCCT), the American Medical Technologists (AMT), or any other recognized certifying body approved by the Board of Medical Examiners. A "clock-hour" shall be calculated at the rate of one hour for every 50 minutes of in-class participation.

"Chronic pain" means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve [page=2382] the pain or its cause and that continues, either continuously or episodically.

"Controlled dangerous substance" means any substance that is listed in Schedules II, III, and V of the schedules provided under the "New Jersey Controlled Dangerous Substances Act," P.L. 1970, c. 226 (N.J.S.A. 24:21-1 et seq.). Controlled dangerous substance also means any substance that is listed in Schedule V under the "New Jersey Controlled Dangerous Substances Act" when the Director has determined that reporting Schedule V substances is required by Federal law, regulation, or funding eligibility, consistent with N.J.A.C. 13:45H.

"Current patient" means any person who is the recipient of a professional service rendered by the practitioner for purposes of diagnosis, treatment, or a consultation related to treatment.

"Data Collection Manual" means the New Jersey Prescription Monitoring Program Data Collection Manual, Version 2.1, incorporated herein by reference, as amended and supplemented, and available on the New Jersey Prescription Monitoring Program website at www.njconsumeraffairs.gov.

"Delegate" means a person authorized to access the PMP information of the practitioner's current or new patient on behalf of a practitioner who is an authorized user of the PMP.

"Dental resident" means a person who practices dentistry as a resident pursuant to N.J.S.A. 45:6-20 and, pursuant to N.J.A.C. 13:30-1.3, is a graduate of a dental school approved by the Commission on Dental Accreditation and has passed Part I and Part II of the National Board Dental examination and obtained a resident permit from the New Jersey Board of Dentistry.

"Director" means the Director of the **Division of Consumer Affairs** in the Department of Law and Public Safety.

"Diversion" means the redirection of a prescription drug from its lawful purpose for illicit use.

"Division" means the **Division of Consumer Affairs** in the Department of Law and Public Safety.

"Emergency department of a general hospital" means an emergency department of a hospital (approved general) licensed and regulated by the Department of Health under N.J.A.C. 8:43G.

"Hospice" means a hospice as defined in N.J.A.C. 8:42C-1.2, which is licensed by the New Jersey State Department of Health.

"Licensed health care professional" means a registered nurse, licensed practical nurse, or dental hygienist licensed pursuant to Title 45 of the Revised Statutes. A "licensed health care professional" also means an advanced practice nurse or a physician assistant who access the PMP as a delegate.

"Medical resident" means a graduate physician who is authorized to practice medicine and surgery by means of a valid permit issued by the State Board of Medical Examiners to a person authorized to engage in the practice of medicine and surgery while in the second year or beyond of a graduate medical education program pursuant to N.J.A.C. 13:35-1.5. For purposes of this subchapter, a medical resident shall not include a licensed physician participating in a graduate medical education program.

"Misuse" means the use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs.

"New patient" means a person who for the first time seeks from or is rendered professional services by the practitioner for purposes of diagnosis, treatment, or a consultation related to a treatment.

"Pharmacy permit holder" means an individual or business entity that holds a permit to operate a pharmacy practice site pursuant to P.L. 2003, c. 280 (N.J.S.A. 45:14-40 et seq.).

"Practitioner" means an individual currently licensed, registered, or otherwise authorized by this State or another state to prescribe drugs in the course of professional practice.

"Registered dental assistant" is a person who has fulfilled the requirements for registration established by the Dental Auxiliaries Act, P.L. 1979, c. 46 (N.J.S.A. 45:6-48 et seq.), as set forth in N.J.A.C. 13:30-2.2, and works under the direct supervision of a licensed dentist.

13:45A-35.3 Pharmacy reporting requirements; electronic format

(a) A pharmacy filling a prescription for a Schedule II, III, IV, or V controlled dangerous substance or for human growth hormone, as defined in N.J.A.C. 13:45A-35.1, in an outpatient setting, shall collect and electronically transmit to the Division's PMP vendor on a daily basis information for each prescription, as specified in the New Jersey PMP Data Collection Manual.

1. For purposes of this section, in accordance with N.J.S.A. 45:1-45 and as specified in the Data Collection Manual, the following information shall be collected and transmitted to the Division:

i. The surname, first name, and date of birth of the patient for whom the medication is intended;

ii. The street address and telephone number of the patient;

iii. The date that the medication is dispensed;

iv. The number or designation identifying the prescription and the National Drug Code of the drug dispensed;

v. The pharmacy permit number of the dispensing pharmacy;

vi. The prescribing practitioner's name and Drug Enforcement Administration registration number;

vii. The name, strength, and quantity of the drug dispensed, the number of refills ordered, and whether the drug was dispensed as a refill or a new prescription;

viii. The date that the prescription was issued by the practitioner;

ix. The source of payment for the drug dispensed; and

x. Such other information, not inconsistent with Federal law, regulation, or funding eligibility requirements, as the Director determines necessary and that is set forth in the Data Collection Manual.

13:45A-35.4 Requests for exemption or waiver

(a) A pharmacy that does not dispense Schedule II, III, IV, or V controlled dangerous substances or human growth hormone, or that dispenses Schedule II, III, IV, or V controlled dangerous substances or human growth hormone only to inpatients in a hospital, long-term or other facility in which the residents are provided with 24-hour nursing care, shall apply to the Division for an exemption from the PMP on a form supplied by the Division and available at www.njconsumeraffairs.gov.

(b) A pharmacy may apply for a waiver of the PMP electronic reporting requirements contained in this subchapter or in the Data Collection Manual for good cause, such as technological limitations or financial hardship, by filing a written application for waiver with the Division on a form supplied by the Division and available at www.njconsumeraffairs.gov. The application for waiver shall document the reasons for the pharmacy's inability to comply with the electronic submission requirement and shall specify the format the pharmacy proposes to use to submit required information to the PMP vendor.

(c) An application for exemption or waiver request granted pursuant to this section shall be valid until June 30 of the following year unless otherwise limited by the Division. If the conditions that necessitated the exemption or waiver are corrected or no longer exist, the pharmacy shall notify the Division, and the exemption or waiver shall become void. If the reasons necessitating the exemption or waiver persist, the pharmacy shall, by June 30 of each year as part of its pharmacy permit or out-of-State pharmacy registration annual renewal application, apply to the Division for a renewal of the exemption or waiver.

13:45A-35.5 Frequency requirements for transmitting information; confidentiality

(a) A pharmacy shall transmit prescription information required by N.J.A.C. 13:45A-35.3 to the PMP vendor on a daily basis pursuant to the schedule established in the Data Collection

Manual. Omissions and errors in the transmitted information shall be corrected and submitted as provided in the Data Collection Manual.

(b) A pharmacy shall transmit the required prescription information in such a manner as to ensure the confidentiality of patient information in compliance with all Federal and State laws, rules, and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996 and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

[page=2383] 13:45A-35.6 Access to prescription monitoring information; retention of information

(a) The Division shall provide online access to prescription monitoring information submitted to the PMP to the following:

1. A pharmacist who is employed by a current pharmacy permit holder and is authorized to dispense controlled dangerous substances or human growth hormone who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient, or verifying information with respect to a prescriber;

2. A practitioner who has a current CDS registration and is authorized to prescribe, dispense, or administer controlled dangerous substances or human growth hormone who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient of the practitioner, or verifying information with respect to a prescriber;

3. A delegate authorized by a practitioner to access the PMP information for the purpose of providing health care to a new or current patient of the delegating practitioner who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient of the delegating practitioner, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

4. A current medical resident of a medical teaching facility who is authorized to access PMP information and who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient at the medical teaching facility for whom the residency program has responsibility of care, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

5. A current dental resident of a dental teaching facility who is authorized to access PMP information and who certifies that the request is for the purpose of providing health care to or verifying information with respect to a new or current patient at the medical teaching facility for whom the residency program has responsibility of care, or verifying information with respect to a prescriber, consistent with the requirements of this subchapter;

6. A designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Optometrists, New Jersey State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this State or another state that regulates the practice of persons who are authorized to prescribe or dispense controlled dangerous substances or human growth hormone, as applicable, who certifies that he or she is engaged in a bona fide specific investigation of a designated practitioner whose professional practice was or is regulated by that board;

7. A designated representative of a state Medicaid or other government program who certifies that he or she is engaged in a bona fide investigation of a designated practitioner, pharmacist, or patient;

8. The State Medical Examiner, a county medical examiner, a deputy or assistant county medical examiner, or a qualified designated assistant thereof, who certifies that the request is for the purpose of investigating a death pursuant to P.L. 1967, c. 234 (N.J.S.A. 52:17B-78 et seq.); and

9. Authorized personnel, as determined by the Director of the Division, responsible for administration of the provisions of P.L. 1970, c. 226 (N.J.S.A. 24:21-1 et seq.);

(b) The Division may provide prescription monitoring information submitted to the PMP to the following, consistent with the purpose certified to by the requester under the requirements of (c) below:

1. A properly convened grand jury pursuant to a subpoena properly issued for the records;

2. Authorized personnel, as determined by the Director of the Division or the PMP vendor responsible for establishing and maintaining the PMP;

3. A State, Federal, or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner, pharmacist, or patient; and

4. A prescription monitoring program in another state with which the Division has established an interoperability agreement, or which participates with the Division in a system that facilitates the secure sharing of information between states.

(c) All persons authorized to have online access to PMP information shall, in accordance with N.J.A.C. 13:45A-35.7, register with the Division and shall receive a login ID and password. Such persons shall complete all forms and statements required by the Division.

1. All persons authorized to have online access to PMP information who become aware or suspect that their login ID and password to the PMP were compromised or used without authorization shall, within five business days of discovering the unauthorized access, notify the Division through the PMP and submit supporting documentation evidencing the unauthorized use.

(d) All persons authorized to have online access to PMP information shall, in accordance with (a) above, prior to each look-up certify to the purpose for which the requested information will be used. The certification shall be completed online in the PMP system.

(e) All persons granted access to PMP information, either through online access or by request, shall comply with all Federal and State laws, rules, and regulations concerning the confidentiality of patient information, including the Federal Health Insurance Portability and Accountability Act of 1996, specifically the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

1. A delegate shall share PMP information with only his or her delegating practitioner.

2. A person granted access to PMP information pursuant to N.J.A.C. 13:45A-35.6(a)6, 7, 8, or 9 may, in the performance of his or her professional duties, share information with

personnel from his or her agency in accordance with agency policy and procedures.

3. In accordance with N.J.A.C. 13:45A-35.8(f), all persons granted online access to the PMP shall not share their PMP login ID and password with any other person or entity.

(f) The Division may provide non-identifying PMP information to public or private entities for statistical, research, or educational purposes, provided that the confidentiality of patient information is not compromised.

(g) Notwithstanding the provisions of this subchapter, the Division may obtain unsolicited automated reports from the PMP or disseminate such reports to pharmacists, practitioners, and other licensed health care professionals.

(h) The Division shall maintain PMP information in such a manner as to ensure the privacy and confidentiality of patient information in compliance with all Federal and State laws, rules, and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164. The Division shall retain PMP information for a minimum of seven years.

1. For purposes of retention in this subsection, "PMP information" shall not include data obtained from other states via an interoperability agreement.

(i) Pursuant to N.J.S.A. 45:1-46, the prescription monitoring information submitted to the Division shall be confidential and not be subject to public disclosure under the State Open Public Records Act, P.L. 1963, c. 73 (N.J.S.A. 47:1A-1 et seq.) or P.L. 2001, c. 404 (N.J.S.A. 47:1A-5 et seq.).

13:45A-35.7 Registration

(a) All persons authorized to have online access to PMP information shall register with the Division. To register, all persons shall:

1. Provide the Division with a unique individual e-mail address.

2. Complete an online tutorial upon initial access to the PMP and as deemed necessary by the Director.

3. Submit all documentation required by the Division to verify the person's identity and credentials. The required documentation shall be listed on the New Jersey Prescription Monitoring Program website at www.njconsumeraffairs.gov.

(b) The Division shall register a practitioner to have online access to PMP information upon issuance or renewal of the practitioner's CDS registration.

[page=2384] 1. Practitioners may also register to access prescription monitoring information outside of their applicable CDS issuance or renewal time period.

13:45A-35.8 Delegates

(a) A practitioner or a faculty member authorized by a medical or dental teaching facility may designate a delegate or delegates for the purpose of accessing PMP information for a new or current patient, or a prescriber, consistent with the requirements of this subchapter.

1. As set forth in this subsection, for each designated delegate, a practitioner or a faculty member authorized by a medical or dental teaching facility is responsible for the use or misuse of the PMP and the prescription monitoring information, ensuring compliance with the recordkeeping requirements, conducting a bi-annual audit, and verifying the education, training, and licensure or certification requirements for each delegate.

2. A delegate may be an authorized delegate for more than one practitioner.

(b) The director of the medical or dental residency program shall designate the faculty members who are authorized to designate medical or dental residents, as applicable, as delegates. The director of the medical or dental residency program shall comply with the recordkeeping provisions of N.J.A.C. 13:45A-35.10.

(c) Delegates may be designated as follows:

1. A practitioner may designate as a delegate a licensed health care professional or a certified medical assistant who is employed at the practice setting at which the practitioner practices.

i. An individual who is no longer employed at the practice setting at which the practitioner practices is no longer authorized to be a delegate or to access the PMP on behalf of that practitioner.

2. A licensed dentist may designate as a delegate a registered dental assistant who is employed at the practice setting at which the licensed dentist practices dentistry.

i. An individual who is no longer employed at the practice setting at which the licensed dentist practices dentistry is no longer authorized to be a delegate or to access the PMP on behalf of that dentist.

3. A faculty member authorized by a medical teaching facility, in accordance with (b) above, may designate as a delegate a medical resident.

i. An individual who is terminated or withdraws from, or completes the graduate medical education program is no longer authorized to be a delegate or to access the PMP.

ii. A medical resident whose program includes training outside the medical teaching facility shall not be designated as a delegate in that setting unless the delegating practitioner has been designated as an authorized faculty member pursuant to (b) above and the residency program retains responsibility of care for the patient for whom healthcare is provided or information is requested.

4. A faculty member authorized by a dental teaching facility may designate as a delegate a dental resident.

i. An individual who is terminated or withdraws from, or completes the graduate dental education program is no longer authorized to be a delegate or to access the PMP.

(d) Prior to designating a delegate, a practitioner or an authorized faculty member of a medical or dental teaching facility shall confirm the education, training, and licensure or certification requirements of each delegate.

1. Prior to designating a delegate, a practitioner or an authorized faculty member of a

medical or dental teaching facility shall ensure that the delegate understands the limitations on disclosure of the prescription monitoring information, and the Federal and State laws, rules, and regulations concerning the confidentiality of patient information, including the Federal Health Insurance Portability and Accountability Act of 1996, specifically the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

2. Prior to designating a certified medical assistant as a delegate, a practitioner shall confirm that that the certified medical assistant has completed a minimum of 600 clock-hours of instruction, and which encompasses training in the administration of intramuscular and subcutaneous injections, as well as instruction and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique, including sterile technique; hazards and complications; and emergency procedures.

(e) A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate is responsible for the use or misuse by his or her delegate of the PMP and the prescription monitoring information. A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate shall:

1. Terminate the delegate's access to the PMP when a delegate, for any reason, is no longer authorized to be a delegate.

2. Terminate the delegate's access and notify the PMP when a practitioner or an authorized faculty member of a medical or dental teaching facility learns of any potential unauthorized use by a delegate of the PMP or prescription monitoring information.

i. The practitioner or authorized faculty member of a medical or dental teaching facility shall, within five business days of discovering the unauthorized access, notify the Division through the PMP and submit supporting documentation evidencing the unauthorized use.

3. Conduct, at least once every six months, audits of the delegate's use of the PMP to monitor for potential misuse of the PMP or prescription monitoring information.

4. Ensure that the delegate follows the recordkeeping procedures established by the practitioner as set forth in N.J.A.C. 13:45A-35.10(a).

(f) All persons authorized to have online access to PMP information shall not share access to the PMP with any other person or entity.

1. All persons granted access to the PMP shall access the PMP using their own unique user login ID and password. The login ID and password shall not be shared with any other person or entity.

2. All delegates shall identify the practitioner on whose behalf they are accessing the prescription monitoring information.

3. All persons authorized to have online access to PMP information may share such information as set forth in N.J.A.C. 13:45A-35.6.

13:45A-35.9 Mandatory look-up

(a) Except as provided in (c) below, a practitioner or the practitioner's delegate shall access prescription monitoring information for a new or current patient consistent with the following:

1. The first time the practitioner prescribes a Schedule II controlled dangerous substance to a new or current patient for acute or chronic pain;

i. When the practitioner or the practitioner's delegate accesses the prescription monitoring information for a new patient in advance of the scheduled appointment, the practitioner or delegate shall document the new patient's request for professional services; and

2. On a quarterly basis during the period of time a current patient continues to receive a prescription for a Schedule II controlled dangerous substance for acute or chronic pain.

i. For purposes of this paragraph, "quarterly" means every three months from the date the initial prescription is issued.

(b) Except as provided in (c) below, if the pharmacist has a reasonable belief that the person may be seeking a controlled dangerous substance, in whole or in part, for any purpose other than the treatment of an existing medical condition, such as for purposes of misuse, abuse, or diversion, a pharmacist shall not dispense a Schedule II controlled dangerous substance to any person without first accessing the prescription monitoring information to determine if the person has received other prescriptions that indicate misuse, abuse, or diversion.

(c) The provisions of (a) ***and (b)*** above***, as applicable,*** shall not apply to:

1. A veterinarian;

2. A practitioner or the practitioner's agent administering methadone as interim treatment for a patient on a waiting list for admission to an authorized substance abuse treatment program;

3. A practitioner administering a controlled dangerous substance directly to a patient;

4. A practitioner prescribing a controlled dangerous substance to be dispensed by an institutional pharmacy, as defined in N.J.A.C. 13:39-9.2;

[page=2385] 5. A practitioner prescribing a controlled dangerous substance in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a five-day supply of the substance;

6. A practitioner prescribing a controlled dangerous substance to a patient under the care of a hospice;

7. A situation in which it is not reasonably possible for the practitioner or pharmacist to access the PMP in a timely manner, no other individual authorized to access the PMP is reasonably available, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

8. A situation under which consultation of the PMP would result in a patient's inability to obtain a prescription in a timely manner, thereby, in the clinical judgment of the practitioner or pharmacist, adversely impacting the medical condition of the patient, and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

9. A situation in which the PMP is not operational as determined by the Division or where it

cannot be accessed by the practitioner or pharmacist due to a temporary technological or electrical failure and the quantity of CDS prescribed or dispensed does not exceed a five-day supply of the substance;

10. A pharmacist who is employed by a pharmacy that, in accordance with N.J.A.C. 13:45A-35.4, has been granted a waiver due to technological limitations that are not reasonably within the control of the pharmacist, or other exceptional circumstances demonstrated by the pharmacist; or

11. A practitioner who is prescribing less than a 30-day supply of a controlled dangerous substance to a patient immediately, but no more than 24 hours, after the patient has undergone an operation, procedure, or treatment for acute trauma, for which a controlled dangerous substance is recognized in the customary treatment of pain following such operation, procedure, or acute trauma.

i. For purposes of this paragraph, "procedure" means an invasive procedure that requires anesthesia.

(d) Prescribing or dispensing of Schedule II CDS after accessing the prescription monitoring information in accordance with (a) or (b) above shall be undertaken if consistent with the practitioner's or pharmacist's professional practice as set forth in the rules of the individual's respective professional licensing board.

13:45A-35.10 Recordkeeping

(a) Each practitioner and each authorized faculty member of a medical or dental teaching facility who designates a delegate shall establish, retain, and follow written procedures to document, as part of the patient record, the PMP look-up as required in N.J.A.C. 13:45A-35.9 and any PMP information accessed for the patient.

1. Each delegate shall follow the documentation procedures established by his or her delegating practitioner.

2. Examples of documentation include a summary notation of the information reviewed by the practitioner or the printed PMP report in the patient record.

3. Once PMP information is documented in the patient record, disclosure of such information is governed by applicable State laws, other than N.J.S.A. 45:1-45, and Federal laws, including the Federal Health Insurance Portability and Accountability Act of 1996 and the Federal health privacy rule set forth at 45 CFR Parts 160 and 164.

(b) A practitioner or an authorized faculty member of a medical or dental teaching facility who designates a delegate shall establish, retain, and follow written procedures to document:

1. Verification of each delegate's education, training, and licensure or certification requirements, as required in N.J.A.C. 13:45A-35.8(d); and

2. The bi-annual audit, as required in N.J.A.C. 13:45A-35.8(e)3.

(c) The program director of the medical or dental residency program shall retain records of the faculty members authorized to designate a medical or dental resident, as applicable, as a delegate.

(d) All records required to be maintained in this subchapter shall be made available to the Division upon request.

13:45A-35.11 Professional misconduct

(a) Noncompliance with the rules in this subchapter may be deemed professional misconduct and may subject the pharmacy permit holder, an out-of-State pharmacy that is subject to this subchapter, pharmacist, practitioner, licensed health care professional, or registered dental assistant to disciplinary action pursuant to the provisions of N.J.S.A. 45:1-21 and to the penalties set forth in N.J.S.A. 45:1-49.

(b) Noncompliance with the rules in this subchapter by a delegate may be deemed professional misconduct by the practitioner and may subject the practitioner to disciplinary action pursuant to the provisions of N.J.S.A. 45:1-21 and to the penalties set forth in N.J.S.A. 45:1-49.

(c) Noncompliance with the rules in this subchapter may provide a basis for the withdrawal of the authorization of a registered resident to engage in the practice of medicine or the practice of dentistry, as applicable. Upon receipt of the notice of proposed withdrawal, the registered resident may request a hearing, which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq.

(d) Noncompliance with the rules in this subchapter may provide a basis for the withdrawal of the authorization to a certified medical assistant to access the PMP. Upon receipt of the notice of proposed withdrawal, the certified medical assistant shall have an opportunity to provide a written explanation for the noncompliance.

(e) The Division shall refer noncompliance with the rules in this subchapter to the appropriate licensing board.

(f) The Division shall refer to law enforcement, which may result in a criminal conviction and a civil penalty in accordance with N.J.S.A. 45:1-49 the following persons:

1. A person who is authorized to obtain prescription monitoring information from the PMP who knowingly discloses such information in violation of the provisions of N.J.S.A. 45:1-45 through 50.

i. The production of a patient record in response to a lawful request by the patient, an authorized representative ***of the patient***, or pursuant to a subpoena or other court order shall not be deemed a knowing disclosure within the meaning of the statute;

2. A person who is authorized to obtain prescription monitoring information who uses this information in the course of committing, attempting to commit, or conspiring to commit any criminal offense; and

3. A person who is not authorized to obtain prescription monitoring information from the PMP who knowingly obtains or attempts to obtain such information in violation of the provisions of N.J.S.A. 45:1-45 through 50.

(g) Notwithstanding the provisions of this subchapter and the person's CDS registration status or employment status, the Division shall retain the right to take action for

noncompliance with the rules in this subchapter or violations of the provisions of N.J.S.A. 45:1-45 through 50.